

# EXHIBIT E

January 7, 2013

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SUPERIOR COURT OF NEW JERSEY  
ATLANTIC COUNTY/CIVIL DIVISION  
DOCKET NO. ATL-L-6966-10

- - -  
LINDA GROSS and JEFFREY GROSS, : STENOGRAPHIC  
Plaintiffs, : TRANSCRIPT OF:  
: :  
v. : :  
: - HEARING -  
GYNECARE, ETHICON, INC., JOHNSON & :  
JOHNSON, and JOHN DOES 1-20, :  
Defendants. : :  
- - -

PLACE: ATLANTIC COUNTY COURTHOUSE  
1201 Bacharach Boulevard  
Atlantic City, New Jersey

DATE: January 7, 2013

B E F O R E:

THE HONORABLE CAROL E. HIGBEE, P.J. Cv.

- - -  
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1 difficult to decide specifically how you draw the  
2 line, but we do know that, you know, overall, that's  
3 not an appropriate approach.

4 THE COURT: To each of these experts  
5 that you've named, you can prepare an order that  
6 indicates that the motion to exclude their testimony  
7 is denied at this time, that the -- without  
8 prejudice to the defense to object to any particular  
9 line of questioning at the time of trial, and that  
10 the witnesses are precluded from making inflammatory  
11 or judgmental statements about the corporation  
12 and/or from stating their own belief as to what the  
13 company's personal interpretation or intent was.  
14 But they can certainly lay it out. They can  
15 certainly define certain words and terms and things  
16 like that, if it's a medical point of view or if  
17 it's, you know, something about a particular  
18 proceeding, they could put it in context.

19 So I really think we have to  
20 basically play it question by question at the time  
21 of trial. But counsel should make sure that its  
22 witnesses understand that both -- you know, when  
23 they were doing this, they were really trying to do  
24 XYZ or they were really trying to hide this or --  
25 you know, that as interpretations are not

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1 appropriate. And we've already really ruled on  
2 that. I think I already said about intent  
3 previously in another motion.

4 So that and inflammatory statements  
5 about their -- this shows how evil they are or, you  
6 know, they were bad actors, or this shows how greedy  
7 they are, anything like that shouldn't be part of an  
8 expert's testimony.

9 MR. SLATER: Understood.

10 THE COURT: So having said that, give  
11 those instructions to your experts. And then if  
12 there's a particular question that you feel is  
13 outside their expertise or a document that you think  
14 the questioning is inappropriate about, we'll just  
15 have to deal with it on a step-by-step basis.

16 MR. ANDERSON: Your Honor, if I  
17 could, please. There's a slight difference between  
18 Dr. Klinge and Ms. Pence and Dr. Weber in that he  
19 was an Ethicon consultant and, therefore, he has  
20 expert testimony, also has fact testimony, because  
21 he worked with them to develop surgical meshes for  
22 greater than ten years. And so there may be some  
23 subtle differences there we need to consider when he  
24 is testifying. I just wanted to raise that to Your  
25 Honor's attention.

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1                   THE COURT: No, I agree.

2                   MR. ANDERSON: Thank you.

3                   THE COURT: I still don't think he  
4 probably would be somebody you would want to use --  
5 we don't still want inflammatory language.

6                   MR. ANDERSON: Correct.

7                   THE COURT: But when it talks about  
8 intent, if he's saying I conferred with the company  
9 officials and this is why we did this, then I think  
10 that that would obviously be an exception.

11                  MR. ANDERSON: Thank you.

12                  THE COURT: Then he's talking about  
13 what his intent was and their intent when they were  
14 dealing with him as to what he specifically said,  
15 but that will be allowed.

16                  MR. SLATER: One other small  
17 question.

18                  These motions that have been filed  
19 before Dr. Shott was videotaped for trial, and I  
20 carefully cautioned her and she was very -- stayed  
21 away from all of it. In fact, her testimony was so  
22 narrow that the defense lawyer had to take some time  
23 to recast the cross because I stayed away from  
24 everything.

25                  The one thing I just wanted to flag

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1 involved in the evaluation of the raw data collected in  
2 a clinical trial to evaluate the safety and efficacy of  
3 a medical device; am I correct?

4 A Correct.

5 MS. JONES: Your Honor, that's all I have.  
6 I do have an objection.

7 THE COURT: Okay. Want to come to sidebar?

8 - - -

9 (The following occurred at sidebar:)

10 MS. JONES: Oh.

11 THE COURT: Do you have another question  
12 for her?

13 MS. JONES: I thought about it. I'll wait.  
14 That's all right.

15 Your Honor, counsel tendered Dr. Weber as  
16 an expert in several areas. I do object to her  
17 testimony with respect to anything regarding the  
18 regulatory aspects of Prolift, the FDA regulations and  
19 whether or not the device complied with the regulations  
20 and whether or not Ethicon complied with the  
21 regulations. I also object on the basis of lack of  
22 qualifications to anything relating to the internal  
23 design process, compliance with the internal design  
24 process, the conduct of that design process by Ethicon.

25 I further object to the testimony with

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1 respect to polypropylene, the biomaterials aspects of  
2 the case, including the porosity of mesh, anything  
3 relating to the pathology of mesh. It's on the basis  
4 of lack of qualification for her to testify in this  
5 area.

6 Now, let me be candid. This witness has  
7 submitted about 600 pages worth of reports in here, and  
8 I'm not sure that Mr. Slater is actually tendering her  
9 as an expert in all of those areas, but I do object to  
10 any regulatory testimony. I object to any testimony  
11 with respect to the design defect -- device design  
12 safety analysis, the FMEA or all of those for total  
13 lack of experience.

14 MR. SLATER: I'll take them one at a time.

15 With regard to FDA regulations, she's not  
16 going to offer any FDA regulatory opinions. In her  
17 testimony she may talk about her familiarity with what  
18 was going on with the company. And all of her  
19 testimony is going to be couched within the  
20 decision-making and the input that would have been or  
21 should have been provided by the medical affairs people  
22 in the company.

23 As Your Honor has started to see in this  
24 case, and I'll give you a regulatory example, one of  
25 the criteria that Sean O'Bryan admitted would have

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1 required him to seek 510(k) clearance would have been  
2 if medical affairs had said that clinical study was  
3 needed in order to establish substantial equivalence or  
4 other criteria for the 510(k) process. She's certainly  
5 qualified to give all those opinions.

6 The person in medical affairs who was  
7 responsible to make all of these decisions when the  
8 Prolift went on the market was four years out of her  
9 residency with no fellowship training, had worked at  
10 three general gynecologic clinics in Florida, had never  
11 operated on her own with mesh, she had participated in  
12 surgeries where she basically assisted another surgeon  
13 who used some mesh a few times with some of her  
14 patients, this is Charlotte Owens, and that was the  
15 person who then made all of the medical affairs  
16 decisions related to the Prolift, including the  
17 decision that it was safe and effective and could be  
18 placed on the market. She gave all of the input to  
19 regulatory affairs they relied on in making their  
20 decision not to seek FDA 510(k) clearance.

21 I'll talk about the design assessments.  
22 Dr. Weber has intimate knowledge of the process. She  
23 is not going to provide an opinion that the process  
24 itself was either good or bad, but what she will do is  
25 provide the testimony that Piet Hinoul has agreed would

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1 come within the purview of medical affairs.

2 I will give you the two prime examples.

3 Number one, the DDSA and FMEA was required to address  
4 all potential hazards and harms or adverse events that  
5 could occur to a woman through the use of the Prolift.  
6 The person in the company who was responsible to make  
7 sure that that was done was Charlotte Owens of medical  
8 affairs.

9 THE COURT: One second.

10 - - -

11 (The sidebar ended.)

12 - - -

13 THE COURT: We'll take a short break and  
14 let the jury take a break.

15 (The jury leaves the courtroom.)

16 - - -

17 (The following occurred at sidebar:)

18 MR. SLATER: Charlotte Owens in medical  
19 affairs was the person in the company required and  
20 relied on to advise and make sure that all of the  
21 potential risks were going to be evaluated. And Piet  
22 Hinoul said, if that wasn't done, the process was  
23 flawed. Dr. Weber will have opinions that Charlotte  
24 Owens failed to make sure that all of the potential  
25 risks were evaluated, because she's been through the

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1 documents. She understands how to read them. She  
2 understands the process -- she's read every single  
3 deposition in this case. She's read every document.  
4 And she's not going to provide an opinion that DDSA is  
5 a good or a bad thing, the FMEA is a good or a bad  
6 thing, but what she's going to say is, Charlotte Owens'  
7 role was to do this.

8 She's certainly qualified to offer opinions  
9 about whether or not a gynecologist with training and  
10 experience that's a small fraction of Dr. Weber's,  
11 whether or not she captured what was needed to be  
12 captured based on the standards the company followed.

13 I'll give you another example. Well, I  
14 mean, that was I think the things that were  
15 specifically addressed.

16 With regard to polypropylene mesh, Dr.  
17 Weber is the co-author of an ACOG practice bulletin  
18 that was published in February of 2007, Clinical  
19 Management Guidelines for the Treatment of Pelvic Organ  
20 Prolapse, in which an analysis was provided of the  
21 emerging polypropylene mesh technology -- the emerging  
22 polypropylene mesh technology. She's named on the  
23 cover of the ACOG practice bulletin, along with another  
24 urogynecologist, Scott Smilen. They made  
25 recommendations to all gynecologists in the United

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1 States who are members of ACOG in this practice  
2 bulletin and drew certain conclusions, including this:

3                 "When choosing the best material for  
4 specific procedures, it is critically important that  
5 surgeons understand how certain characteristics of  
6 materials play a key role in the risk/benefit ratio for  
7 various types of surgery. Pore size in surgical mesh  
8 is one of the most important factors determining risk  
9 of postoperative infection."

10                 I'm just reading some quotes from this.

11                 Another part of it.

12                 "Although several studies have evaluated  
13 anterior colporrhaphy with and without mesh or graft  
14 materials of different types, because of heterogeneity  
15 of materials studied, small sample sizes and short-term  
16 follow-up, it is not possible to draw definitive  
17 conclusions about the risk versus the benefit of  
18 absorbable or permanent synthetic materials in anterior  
19 colporrhaphy."

20                 "Given the limited data and frequent  
21 changes in the marketed products, particularly with  
22 regard to type of mesh material itself, which is most  
23 closely associated with several of the postoperative  
24 risks, especially mesh erosion, the procedures should  
25 be considered experimental and patients should consent

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1 to surgery with that understanding."

2 She is the person who is recognized on the  
3 cover of this practice bulletin. It says, and I'll  
4 give the specific cite for the record, this is Clinical  
5 Management Guidelines for Obstetrician & Gynecologists,  
6 ACOG practice bulletin number 79, February 2007, volume  
7 109, number 2, part 1.

8 "This practice bulletin was developed by  
9 the ACOG committee on practice bulletins, gynecology  
10 with the assistance of Scott W. Smilen, MD and Anne M.  
11 Weber, MD, MS. The information is designed to aid  
12 practitioners in making decisions about appropriate  
13 obstetric and gynecologic care."

14 That's in part what it says.

15 So she has been instrumental in looking  
16 into this field. Practice bulletins, as Your Honor I'm  
17 sure is aware, in ACOG are given a lot of respect and a  
18 lot of importance. They're read, they're looked at.  
19 So Dr. Weber certainly has the ability to comment on  
20 anything within the company that medical affairs was  
21 involved in, because that is the field that she is in.  
22 Certainly no one is disputing her expertise in that.

23 Again, Charlotte Owens was the person who  
24 made all of the critical medical decisions within the  
25 company that were relied on by regulatory, quality

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1 engineering, marketing, a whole host of issues. Every  
2 major issue in this case, it ended up on Charlotte  
3 Owens' desk. And Dr. Owens' testimony, she certainly  
4 can testify to her understanding of the processes and  
5 then focus her opinions down.

6 I was talking about design control before.  
7 Number one, her opinion is they did not come close to  
8 evaluating all of the potential risks and adverse  
9 events that could have resulted from the Prolift.  
10 Chapter and verse. And she has more than enough  
11 qualification to give those opinions, because Charlotte  
12 Owens was the one who signed off.

13 Number two, the clinical expert report,  
14 which we've been through in this trial now, she  
15 absolutely is qualified to talk about the inadequacy of  
16 that clinical expert report as an evaluation of the  
17 available clinical evidence at the time and whether or  
18 not that clinical evidence provides a favorable  
19 risk/benefit ratio such that the Prolift should have  
20 been cleared by Charlotte Owens of medical affairs to  
21 go to PRA and be marketed. Her opinions will be  
22 couched within her expertise and within her profession  
23 and her specialization.

24 When it comes to study design, nobody is  
25 going to argue with her qualifications. She started

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1       the area in the NIH to fund NIH studies of  
2       urogynecologic surgery and disorders. She is more than  
3       qualified to comment on the clinical studies that were  
4       performed. If counsel wants to say it goes to the  
5       weight, because she hadn't personally done a study of  
6       the Prolift or of mesh, hey, have at it. I think it's  
7       going to be more than apparent to the jury that her  
8       expertise, which was brought to this and reading  
9       hundreds and hundreds of thousands of pages of internal  
10      documents, reading every single deposition in this case  
11      by every person involved, reading a pile of medical  
12      literature that is astounding, she has spent over 2,000  
13      hours working on this case. That's more than 83  
14      consecutive days. And they're going to put on experts  
15      who haven't looked at any of these materials.

16                   So she has more than adequate basis and  
17                   more than adequate -- and we're talking about now about  
18                   her expertise, but any opinion -- and, again, medical  
19                   affairs, clinical study and design, that is exactly  
20                   what she is.

21                   THE COURT: Well, it appears to me that  
22                   you've addressed any concerns raised about her ability  
23                   to testify about everything that happened within the  
24                   company as far as their studies, whether they were  
25                   adequate, inadequate. She's obviously a specialist in

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1       designing studies and evaluating, and she has the  
2       educational background and the ability to do that. The  
3       fact that she herself has not designed a product, those  
4       all go to the weight of her testimony.

5                  The only area that I'm concerned about is  
6       the regulatory and the 510(k) approval and -- because  
7       she really doesn't see --

8                  MR. SLATER: I'll tell you what -- I'm  
9       sorry to interrupt, because I know time is valuable.

10                 THE COURT: Let us know what we're going to  
11      do with that.

12                 MR. SLATER: This is what she's going to  
13      say. She is not going to provide an opinion that they  
14      needed to get 510(k) clearance. Okay? That's Dr.  
15      Pence, who is going to testify next week.

16                 But there's two areas that she is more than  
17      qualified and a few areas that relate to that.

18                 Number one, the question of whether or not  
19      Gynemesh and the Prolift are essentially the same  
20      thing. She's certainly qualified to talk about the  
21      differences from a clinical standpoint in terms of the  
22      surgical procedures, in terms of how this would  
23      interact with the body, in terms of the -- now you're  
24      taking -- she can certainly differentiate them, not in  
25      a regulatory standpoint, but from a medical surgical

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1       standpoint, what a surgeon would think when looking at  
2       these and say what's the same, what's different. And  
3       that's one thing.

4                     THE COURT: She's someone who is an expert  
5       in surgical procedures, and I have no problem with her  
6       testifying to the difference in the surgeries between  
7       the two, whether she's performed them or not, and in  
8       the difference in the -- well, the difference in the  
9       procedures, the difference in the complications, the  
10      difference in the way they're performed, the  
11      differences in between the materials themselves, that  
12      she would be qualified to do.

13                  When it gets into did this -- what is  
14      510(k), how would -- do you intend to address the FDA  
15      with her?

16                  MR. SLATER: The only way that I intend to  
17      address that question is this. She's aware of the  
18      regulatory status. It's a fact in the case. There's  
19      documents and there's testimony that establishes what  
20      happened at what time. I will ask her, does she have  
21      an opinion as to whether or not a reasonable  
22      urogynecologist, gynecologist or urologist, what they  
23      would have done if they knew the facts. Would it be  
24      significant to a surgeon to know that a product or a  
25      system, the ProLift, was or was not cleared if that was

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1       necessary. I'm going to ask her to assume certain  
2       facts and say, assuming those facts, do you have an  
3       opinion as to whether a reasonable surgeon in this  
4       field would or would not use any medical device knowing  
5       that. And, in fact, she doesn't have to only rely on  
6       something in the abstract, she has the testimony of Dr.  
7       Benson, the implanting surgeon, who says I wouldn't  
8       have used it. She has the testimony of Vincent  
9       Lucente, their US investigator, their most important  
10      key opinion leader, says, I wouldn't have used it, I  
11      didn't know. David Robinson, their medical affairs  
12      director, who says, I would have had to take a close  
13      look at it, who while he was an investigator and then  
14      was using the product after launch, never knew it  
15      didn't have clearance.

16                   So she has facts to rely on from multiple  
17      people who were employed by the company. Axel Arnaud  
18      parenthetically found out last year it wasn't cleared.

19                   So she has the absolute ability to give  
20      that opinion of what a surgeon in this field would or  
21      would not have thought was significant in whether to do  
22      a surgical procedure. She has more than enough of a  
23      foundation for it. And she's not going to give an  
24      opinion as to whether or not 510(k) clearance was  
25      needed or not. Not her field, not going to ask the

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1 question.

2 MS. JONES: That is absolutely irrelevant  
3 in this case. What's important in this case is what  
4 Dr. Benson testified to, period. And she -- what any  
5 reasonable surgeon other than Dr. Benson --

6 MR. SLATER: Then I ask for a directed  
7 verdict on failure to warn and deceit right now. I'd  
8 like a directed verdict. If counsel says the only  
9 thing that matters is what Dr. Benson said, his trial  
10 testimony is locked in stone now, he said he wouldn't  
11 have used it. Therefore, I ask for a directed verdict.

12 MS. JONES: That is -- Your Honor, his  
13 testimony will come in at the appropriate time in the  
14 appropriate manner when Your Honor rules.

15 Now, the --

16 THE COURT: Well, the argument as to  
17 whether it was, quote, experimental to a degree or  
18 whether it was in fact simply an extension of a prior  
19 procedure that had been done, I think first -- I think  
20 that clearly falls within her expertise as a surgeon  
21 who's performed numerous different types of surgery and  
22 who specialized in the type of repairs that we're  
23 talking about, so I'm going to allow her to do that.

24 As to whether what a reasonable surgeon  
25 would do if advised, I think that is part of it and is

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1 appropriate. Obviously, the jury is going to give  
2 great weight, I'm sure, to what Dr. Benson said, but in  
3 evaluating the credibility of Dr. Benson and evaluating  
4 the statements that were made by him, I think that part  
5 of her expertise goes to what surgeons would have  
6 understood, would not have understood, what they would  
7 have wanted to know, why they would have wanted to know  
8 it. She's coming at it from the point of view of a  
9 surgeon. I'm going to allow her to give that  
10 testimony.

11 All right. We'll proceed. And if there's  
12 any objections to any particular questions, you can  
13 make them, obviously. And the objection to her  
14 speaking about the regulatory process is -- I'm  
15 sustaining that objection as far as the process itself,  
16 as far as what the process is, what the 510(k)  
17 requires, what -- whether they did or did not comply.  
18 Counsel's indicated she's not going to be asked about  
19 that, and so the regulatory process, I think, which she  
20 has limited qualification in, I grant that motion.

21 The motion as to the design of the product  
22 itself and whether a surgeon would have been able to  
23 work with it and how it would affect, I'm going to  
24 allow. All right.

- - -